UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/627,633 | 07/28/2003 | Andrew David Charles | 1991-221 | 3325 |

6449 7590 10/17/2005

ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

| EXAMINER | |
|---|---|
| SULLIVAN, DANIEL M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1636 | |

DATE MAILED: 10/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/627,633 | CHARLES ET AL. | |
| | Examiner | Art Unit | |
| | Daniel M. Sullivan | 1636 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.



1005

## DETAILED ACTION

Claims 1-21, as originally filed, are pending.

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 12, 16-18 and 21, drawn to a method for provision of an appetite control agent comprising testing an agonist or antagonist of GPR19 and selecting an active compound as an appetite control agent, classified in class 435, subclass 4.

II. Claims 4 and 6, drawn to a method of appetite control comprising administering an agonist of a GPR19 receptor, classified in class 514.

III. Claims 5 and 6, drawn to a method of appetite control comprising administering an antagonist of a GPR19 receptor, classified in class 514.

IV. Claims 7 and 8, drawn to an appetite control agent comprising an antisense nucleic acid complementary to SEQ ID NO: 1, classified in class 536, subclass 24.5.

V. Claims 7 and 8, drawn to an appetite control agent comprising an antisense nucleic acid complementary a to nucleic acid other than SEQ ID NO: 1, classified in class 536, subclass 24.5.

VI. Claims 9-11, drawn to a transgenic animal in which a GPR19 gene is modified, classified in class 800, subclass 8.

VII. Claim 13, drawn to a dominant negative mutant of a GPR19 receptor, classified in class 530, subclass 350.

VIII. Claim 14, drawn to a dominant positive mutant of a GPR19 receptor, classified in class 530, subclass 350.

IX. Claim 15, drawn to a method of evaluating the biological role of the GPR19 receptor in appetite control using the mutant of Groups VII or VIII, classified in class 530, subclass 350.

X. Claim 19, drawn to a method comprising determining the expression level of GPR19, classified in class 435, subclass 6.

XI. Claim 20, drawn to method comprising determining an allelic variant of the GPR19 gene, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Groups IV-VI, VII and VIII are directed to structurally and functionally distinct products. Group IV is directed to a nucleic acid molecule having the structure and function of antisense nucleic acid complementary to the nucleic acid set forth as SEQ ID NO: 1. None of the products of the other Groups share these structural or functional properties. Likewise, Group V is directed to a nucleic acid molecule having the distinct structural and functional properties of an antisense nucleic acid complementary to the nucleic acid set forth as SEQ ID NO: 1, which properties are not comprised by the products of the other Groups. (Claims 7 and 8 recite an embodiment wherein the antisense is complementary to SEQ ID NO: 2; however, SEQ ID NO: 2 is a polypeptide sequence. Therefore, it is assumed for the purpose of this restriction requirement that the nucleic acid referred to is SEQ ID NO: 3 or SEQ ID NO: 5, either of which are distinct from

SEQ ID NO: 1). Group VI is directed to a transgenic animal having a mutated GPR19 gene; Group VII is directed to a dominant negative mutant of a GPR19 receptor; and Group VIII is directed to a dominant positive mutant of a GPR19 receptor. Each of these products is limited to comprising structural and/or functional properties not comprised by any of the other claimed products. As each product is structurally and functionally distinct, the products comprise a distinct mode of operation, function or effect, which distinguishes the products, each from the other.

Given that the products do not share a common structure and function, the features that define each product must be searched independently and, absent evidence to the contrary, the disclosure of any one product does not render obvious the product of the remaining Groups. Likewise, a determination that any one of the products is free of the art does not evidence the patentability of the other products. Therefore, because examination of each product requires a separate search, examination of Groups IV-VI, VII and VIII together in a single application would impose a serious burden on the Office.

Groups I-III and IX-XI are directed to processes limited to having distinct outcomes and are therefore presumed to have different modes of operation, function and/or effect. Group I is directed to a method comprising selecting an active compound for use as an appetite control agent, which is not a function or effect of any of the other methods. Likewise, the processes of Groups II and III are directed to a method of for appetite control, which function and effect would not result from any of the other methods. In addition, although the methods of Groups II and III recite the same outcome, the methods are limited to administering compounds having mutually exclusive properties (*i.e.*, agonist *versus* antagonist). Therefore, the methods of Groups

II and III have distinct modes of operation in that they are limited to administration of distinct agents. The claims of Groups IX-XI do not recite any process steps and therefore do not properly define the subject matter claimed. However, in view of the distinct outcomes recited in the claims, it is presumed that the processes have different modes of operation, function and/or effect with respect to each other and the processes of groups I-III.

In the absence of an allowable product claim to which the process claims are limited to making or using, examining the methods of Groups I-III and IX-XI together in a single application would impose a serious burden on the Office. As each method is limited to comprising elements and/or providing an outcome to which the other methods are not limited, examination of each method requires a separate search for those elements that distinguish the respective methods. In addition, because each method encompasses subject matter not encompassed by the other methods, a determination that any one method is patentable over the art does not adequately support patentability of any of the other methods. Therefore, patentability of each method must be determined separately.

Inventions VI and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the transgenic animal can be used in materially different processes such as to study the metabolic effects of GPR19 modification. Furthermore, the process of Group I can be practiced using a materially different product such as a cultured cell.

Likewise, although Inventions VII and VIII are related to invention IX as product and process of using, the products can be used in materially different processes such as to raise an antibody against a GPR19 receptor or to study properties of GPR19 that are unrelated to appetite control.

Although the Office acknowledges that in the event a product claim is deemed allowable, determining patentability of process claims that depend from or otherwise include all the limitations of the allowable product claim does not impose an undue burden (see below), no such determination of patentability has been made in the instant case. In the event that the product is not patentable, a determination of whether each method of making and using the product is patentable over the art is based upon the particulars of the method and not on the product made by or used in the method. Conversely, a search of any given process of making or using the product does not adequately support patentability of the product because the product can be made by or used in a materially different process. Therefore, until the product is deemed allowable, search and examination of the process claims with the product imposes an undue burden on the Office. As discussed in detail below, if a product claim is found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04.

Finally, the products of Groups IV and V are unrelated to the processes of Groups I-III, and IX-XI; the product of Group VI is unrelated to the processes of Groups I, III and IX-XI; and the product of Groups VII and VIII are unrelated to the processes of Groups I-III, X and XI because the products are neither made by nor used in the respective processes. As the products and processes are unrelated and therefore might be disclosed independently of one another, a

search and examination of the unrelated inventions together in a single application would constitute an undue burden on the Office.

Rejoinder in view of *In re Ochiai, In re Brouwer*

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to

retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

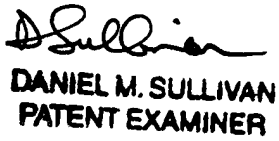
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M. Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M Sullivan, Ph.D.
Examiner
Art Unit 1636



DANIEL M. SULLIVAN
PATENT EXAMINER